

Appl. No. 09/834,410
Amdt. dated August 15, 2003
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group

PATENT

1 **Amendments to the Claims:**

2 This listing of claims will replace all prior versions, and listings, of claims in the application:

3 **Listing of Claims:**

4 1. (Currently amended) A timed-release compression-coated solid composition for oral
5 administration to a subject, said composition comprising:

6 a) a core tablet comprising a drug and a freely erodible filler, wherein said core
7 tablet is capable of erodes approximately 40% to approximately 90% erosion in the digestive
8 tract of said subject; and

9 b) an outer layer, said outlayer wherein said outer layer is made from a hydrogel-
10 forming polymer substance, and a hydrophilic base, wherein said outer layer optionally contains
11 a drug-hydrogel-forming polymer substance has a viscosity-average molecular weight of
12 2,000,000 or higher and/or a viscosity in an aqueous 1% solution (25° C) of 1,000 cp or higher,
13 and said hydrophilic base having solubility such that the amount of water needed to dissolve 1g
14 of said hydrophilic base is 5 mL or less; and

15 c) wherein the outer layer optionally contains another drug and the outer layer
16 essentially does not contain the same drug as the core tablet drug.

1 2. (Cancel)

1 3. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein there is approximately 75 wt% or less of said drug,
3 approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to
4 approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to
5 approximately 80 wt% hydrophilic base.

1 4. (Original) The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected
3 from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol, sucrose,
4 and lactulose.

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- 1 5. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.
- 1 6. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.
- 1 7. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for an acidic or neutral drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or lactulose.
- 1 8. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance contains at least one type of polyethylene oxide.
- 1 9. (Cancel)
- 1 10. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the core tablet contains hydrogel-forming polymer substance.
- 1 11. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrophilic base is 1 or 2 or more having solubility such that the amount of water needed to dissolve 1 g base is 5 mL or less.
- 1 12. (Original) The timed-release compression-coated solid composition for oral administration according to claim 11, wherein the hydrophilic base is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose, and lactulose.

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- 1 13. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance is at least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric oxide.
- 1 14. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effectively released or absorbed in the lower digestive tract.
- 1 15. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effective for chronopharmacotherapy.
- 1 16. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is metabolized by cytochrome P-450.
- 1 17. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug has the effect of inhibiting metabolism by cytochrome P-450.
- 1 18. (Original) The timed-release compression-coated solid composition for oral administration according to claim 16, wherein the drug is metabolized by CYP3A4.
- 1 19. (Original) The timed-release compression-coated solid composition for oral administration according to claim 17, wherein the drug has the effect of inhibiting metabolism by CYP3A4.
- 1 20. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the drug is 4'-[²-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl]carbonyl]-2-phenylbenzanilide or its salt.
- 1 21. (Original) A method of timed release of a drug, whereby the composition in claim 1 is orally administered.

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- 1 22. (Original) A method for alleviating undesirable drug interaction between a drug and
- 2 other drugs used concomitantly that employ the same route for drug absorption, distribution,
- 3 metabolism or excretion *in vivo* in humans, whereby the composition in claim 1 is orally
- 4 administered.

- 1 23. (Original) A method of alleviating undesirable drug interaction with between a drug
- 2 having the effect of inhibiting drug metabolism *in vivo* in humans and another drug according to
- 3 claim 20 used concomitantly, whereby the composition in claim 1 is used.

- 1 24. (Original) In a hydrogel-forming compression-coated solid pharmaceutical
- 2 preparation comprising: a core tablet containing drug and outer layer made from hydrogel-
- 3 forming polymer substance and hydrophilic base, the improvement which comprises a timed-
- 4 release compression-coated solid composition according to claim 1.

- 1 25. (Original) In a hydrogel-forming compression-coated solid pharmaceutical
- 2 preparation comprising:
 - 3 a core tablet containing drug and outer layer made from hydrogel-forming polymer
 - 4 substance and hydrophilic base, the improvement which comprises a timed-release compression-
 - 5 coated solid composition for oral administration, said composition comprising:
 - 6 (1) a drug and freely erodible filler are mixed with the core tablet;
 - 7 (2) the percentage erosion of the core tablet is approximately 40 to approximately 90%;
 - 8 and
 - 9 (3) the outer layer essentially does not contain the same drug as the above-mentioned
 - 10 drug.

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26. (Original) The timed-release compression-coated solid composition for oral administration according to claim 25, wherein the drug is 4'-[¹(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzamilide or its salt.